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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,694	08/07/2001	Atsushi Suzuki	210377US0	8724

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EXAMINER
EVANS, CHARESSE L

ART UNIT	PAPER NUMBER
1615	

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7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/922,694	Applicant(s) SUZUKI ET AL.	
	Examiner Charesse L. Evans	Art Unit 1615	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-19 are active.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 6, and 8-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,310,100 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions disclose treatments for hypertension comprised of ferulic acid or a derivative thereof. The therapeutic compositions comprising ferulic acid and its derivatives may further comprise pharmaceutical products, nutritional supplements or products, and foods.

Claims 1-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3-6 of copending Application No. US 2002/0054923 A1; over claims 1 and 3-6 of copending Application No. EP 1186297 A2; over claims 1-17 of copending Application No. EP 1186294 A2; and over claims 1, 2 and 5-10 of copending Application No. EP 1090635 A2. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions disclose

agents for treating hypertension comprised of caffeic acid, chlorogenic acid and ferulic acid and esters and pharmaceutically acceptable salts thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6, 8 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "and/or" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,261,565 B1 (Empie et al). The claims are directed to products and compositions for reducing the severity of hypertension containing ferulic acid or a ferulate ester and caffeic acid and/or chlorogenic acid.

Empie teaches an invention for the refinement of phytochemicals by extracting phytochemicals from plant matter. The composition is enriched in two or more isoflavones, lignans, saponins, catechins and phenolic acid (Abstract and column 2, lines 3-6). Phenolic acids include chlorogenic acid, caffeic acid, ferulic acid and cinnamic acid (column 3, lines 3-6). The disclosed invention may be used alone or in combination with one or more other plant extracts to produce the optimized

composition. The extract composition may be formulated with one or more other dietary nutrients, such as vitamins, minerals, amino acids to provide a nutritional supplement further optimized for a desired health effect. The phytochemicals may be packaged and provided in final form by means known to supplement and food ingredient industries (column 3, lines 66 bridging column 4, lines 1-13).

The reference does not teach that the phenolic acids are to be used for treating or preventing hypertension, however, the reference teaches that phenolic acids have shown antioxidant activity (column 2, line 47). The presence of free radicals has been suggested as contributors to hypertension within the human body. Therefore, it would have been obvious to one of ordinary skill within the art at the time of the invention to modify the teachings of the cited prior art with the expectation that there will be an effect on lipid peroxidation within the low-density lipoproteins characteristic in the vascular tissue of hypertensive patients.

Claims 1-6, 8 and 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,932, 623 (Tanabe et al). Tanabe discloses a fruit polyphenol obtained by subjecting unripe fruits of Rosaceae, particularly unripe apples, pears or peaches, to pressing or extraction and then purifying the resulting juice or extract 9column 3, lines 39-43). The fruit polyphenol obtained by the disclosed process is composed mostly of caffeic acid derivatives, p-coumaric acid derivatives, catechins, quercetin glycosides and the like as well as high molecular polyphenol compounds

such as condensed tannins and the like (column 4, lines 34-41). The fruit polyphenol of the disclosed invention contains a large amount of a component capable of inhibiting the oxidation of linoleic acid and a large amount of a component capable of inhibiting the function of ACE, which is an enzyme connected with an increase in blood pressure (column 4, lines 45-54).

Conclusion

No claims are allowed at this time.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- Cirigliano et al (US 6,120,823) discloses a foodstuff having selected flavorant/antimicrobial compounds; and
- Lansendorfer et al (US 6,423,747 B1) discloses cosmetic and dermatological preparations with flavonoids.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charesse L. Evans whose telephone number is 703-308-6400. The examiner can normally be reached on Monday - Thursday 7:00a - 4:30p; Alternating Fridays 7:00a - 3:30p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Charesse Evans
September 19, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600